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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,356	01/12/2006	Shin Yazawa	283520US0PCT	7829
22850	7590	05/10/2007	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			PESELEV, ELLI	
		ART UNIT	PAPER NUMBER	
		1623		
		NOTIFICATION DATE	DELIVERY MODE	
		05/10/2007	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/564,356	YAZAWA ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Elli Peselev	1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 05 March 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 5-53 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 5-53 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

Art Unit: 1623

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Japanese Patent (11-60592) or the Japanese Patent (200-191685) in view of Endo et al (U.S. Patent No. 6,569,464).

Each of the Japanese patents discloses cholestanol glycosides useful as anticancer agents but does not disclose said agents in liposome formulation. However, Endo et al disclose that "liposomes encapsulating drugs have been actively developed for the purposes of stabilization of unstable drugs, slow release of drugs in living bodies and targeting of drugs to lesion sites" (column 1, lines 15-25). Endo et al further disclose liposomal compositions comprising a wide variety of drugs, phospholipids and a positive-charge-providing substance such as cholesterol, aliphatic amines and fatty

Art Unit: 1623

acids such as stearylamine and oleic acid (column 2, lines 30-56, column 4 and column 5, lines 1-15). Endo et al also teach that the drugs contained in the liposomes disclosed are not limited and may either hydrophilic or lipophilic (column 3, lines 56-59). Therefore, a person having ordinary skill in the art at the time the claimed invention was made to prepare formulations of drugs disclosed by the Japanese Patents in liposomal formulations as disclosed by Endo et al in order to improve stabilization of said drugs and to slow release said drugs.

Claims 32-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarkar et al (The Journal of Biological Chemistry, vol. 272, vol. 41, pages 25608-25616, 1997) in view of Endo et al (U.S. Patent No. 5,569,464).

Sarkar et al disclose naphthalene glycosides drugs but do not disclose said compounds in liposome form. However, since Endo et al disclose the advantage of preparing a wide variety of drugs in liposomal form as discussed above, a person having ordinary skill in the art at the time the claimed invention was made would have been motivated to prepare drugs disclosed by Sakar et al in liposomal formulations.

Claims 43-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akimoto et al (U.S. Patent No. 5,849,716) in view of Endo et al (U.S. Patent No. 5,569,464).

Akimoto et al disclose ceramide glycosides drugs having anti-tumor activity (column 1, lines 45-67 and column 2, lines 1-40) but do not disclose said drugs in liposome formulation. However, since Endo et al disclose the advantage of preparing a wide variety of compounds in liposomal formulation as discussed above, a person

having ordinary skill in the art at the time of the claimed invention would have been motivated to prepare said drugs in liposomal form.

Applicant's arguments filed March 5, 2007 have been fully considered but they are not persuasive.

Applicants contend that the Japanese Patents and Sarkar et al do not disclose incorporating said compounds into a liposomal composition. This argument has not been found persuasive because the advantage of incorporating drugs into liposomal compositions was well known in the art at the time the claimed invention was made as disclosed by Endo et al. Applicants further contend that Sarkar et al disclose utilizing a naphthalenyl glycoside as an anti-inflammatory agent and not an anti-tumor agent. This argument has not been found persuasive since the present claims are directed to compositions and not to methods of use. In response to applicant's argument that Sarkar et al do not disclose the use of naphthalenyl glycosides as anti-tumor agents, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Applicants also contend that a skilled artisan would reasonably expect that the cholestanyl glycosides of the present invention would intrinsically possess sufficient affinity to cellular membranes without the aid of a liposomal carrier. This argument has not been found persuasive because Endo et al disclose the advantage of liposome

Art Unit: 1623

formulations other than he affinity to cellular membranes such as slow release of drugs and targeting of drugs (column 1, lines 15-25).

Applicants also contend that inventor have unexpectedly discovered that by incorporating the cholestanyl glycoside anticancer agents into the liposomal carrier, the liposomal composition of the present invention exhibited enhanced antitumor efficacy as shown in Figures 1 and 2. This argument has not been found persuasive since the claims have not been limited to the compounds shown in Figures 1 and 2 i.e. the data shown in Figures 1 and 2 is not commensurate in scope with the claimed invention.

Applicants also contend that Endo et al disclose incorporating a carcinostatic active agent into a liposomal composition, said carcinostatic agent is present in a laundry list of more than twenty widely diversified types of active gents and that there is a lack of motivation to pick and chose agents therefrom. Applicants also contend that the anti-cancer agents disclosed by Endo et al are vastly different in chemical structure in comparison with the claimed compounds. This argument has not been found persuasive since Endo et al disclose incorporation into liposomes not only of anti-cancer drugs but a wide variety of other drugs and teach that the "drugs to be contained in the liposomes of the present invention are not particularly limited and may be either hydrophilic or lipophilic" (column 3, lines 56-59). Endo et al also disclose incorporating into liposomes hormonal preparations (column 4, lines 35-40) which have structurally similar to the cholestanol.

Therefore, the claimed compositions are still deemed prima facie obvious over the cited prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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